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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,067	06/19/2001	Peter Jan Leonard Mario Quaedflieg	246152014600	1020

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/869,067	Applicant(s) QUAEDFLIEG ET AL.	
	Examiner Christian L Fronda	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/12/02</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1652

DETAILED ACTION

Election/Restriction

1. Applicants' election of Group I in the reply filed on 12/02/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1 and 3-12 are under consideration in this Office Action.
3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.
4. The disclosure is objected to because of the following informality: in the specification there is no statement that indicates that the instant application is the US National Stage filing of PCT Application No. PCT/NL99/00782, filed 12/17/1999, which claims foreign priority under 35 U.S.C. 119(a)-(d) to foreign patent application EPO 98204370.5 filed on 12/22/1998. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
Claims 5 and 6 recite the limitation "peptide deformylase". There is insufficient antecedent basis for this limitation in these claims. It appears that claims 5 and 6 should depend from claim 4.

Art Unit: 1652

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1 and 3-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 3, and 10-12 are genus claim that is directed toward a genus of acylases that are used in a process for preparing alpha-aminonitriles. The scope of these claims include many acylases with widely differing structural, chemical, and physical characteristics from many biological sources. Furthermore, the genus is highly variable because a significant number of structural differences between genus members exists.

Claims 4-9 are genus claim that is directed toward a genus of peptide deformylases including from the class EC 3.5.2.27 or EC 3.5.1.31 that are used in a process for preparing alpha-aminonitriles. The scope of these claims include many acylases with widely differing structural, chemical, and physical characteristics from many biological sources. Furthermore, the genus is highly variable because a significant number of structural differences between genus members exists.

The specification discloses the isolation of the *E.coli* peptide deformylase and its use in the deforymlation of N-formyl-valine aminonitrile, N-formyl-m-methoxy-phenylalanine aminonitrile, and N-formyl-phenylalanine aminonitrile. However, the specification fails to provide a written description of additional acylases and peptide deformylases and their common structures which can be used in the claimed process. Neither the specification nor the general knowledge of those skilled in the art provide evidence of any amino acid sequence and structure which would be expected to be common to the members of the genus.

A sufficient written description of a genus of acylases and peptide deformylases may be achieved by a recitation of a representative number of acylases and peptide deformylases defined by amino acid sequence or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Claim 6 does not recite a description of a substantial portion of the claimed genus of peptide deformylases, and thus does not meet the written description requirement. Claim 7 does not meet the written description requirement because there is not description of a common amino acid sequence and structure of peptide

Art Unit: 1652

deformylases that is from *Escherichia coli*.

In view of the above considerations, one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by members of the genus. Accordingly, Applicant has failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicant was in possession of the claimed a genus of acylases and peptide deformylases that are used in a process for preparing alpha-aminonitriles with enhanced optical purity.

Claim Rejections - 35 U.S.C. § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Romeo et al. (Tetrahedron Letters. 1971; 21: 1799-802) in view of Drummond et al. (Anal Biochem. 1995 Jul 1;228(2):323-9).

Romeo et al. teach a process comprising contacting the *E.coli* benzylpenicillin acylase with racemic mixtures of N-phenylacetyl derivatives including N-phenylacetyl-aminobutyronitrile for producing a specific isomer (see entire publication, especially Table 1 and Table 2).

Claims 1 and 3 differ from the teachings of Romeo et al. in that a formylating agent is provided.

Drummond et al. teach a process step for formylating tetrahydrofolate using formic acid (see entire publication, especially, p.324, left column, last paragraph to p. 326).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Romeo et al. such that N-phenylacetyl-aminobutyronitrile isomer produced by the action of the *E.coli* benzylpenicillin acylase is contacted with the formic acid (formylating agent) as taught by Drummond et al.

Art Unit: 1652

One of ordinary skill in the art at the time the invention was made would have been motivated to do this for the purposes of producing a beneficial method that can synthesize formylated N-phenylacetyl-aminobutyronitrile isomers.

No patentable weight is given to the preamble of process claims 1 and 3 since it merely recites the purpose of these process claims. Thus, the process steps taught by the modified method of Romeo et al. render obvious these process claims because these process steps are the same as the process steps recited in claims 1 and 3. Because the process steps in claims 1 and 3 are the same as the process steps in the modified method of Romeo et al., then the modified method of Romeo et al. would inherently produce the alpha-aminonitriles with enhanced optical purity.


Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF



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